510 (k) Summary
As Required by 21 section 807.92 (c)

1. **Submitter Name:** Siam Sempermed Corp., Ltd
2. **Address:** 352 Kanjanavanit Road. Pahtong Hatyai Songkhla.Thailand 90230
3. **Phone:** (+66) 74 291 471
4. **Fax:** (+66) 74 471 111
5. **Contract Person:** Mrs. Parawan Paiyasan (Quality System manager)

JUL - 9 2010

6. **Date summary prepared:** 15 March , 2010
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North Clearwater, USA , FL 33762
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E. Harris
12. **Device Trade or Proprietary Name:** Non-sterile, powder-free latex examination gloves and protein claim (50 micrograms or less).
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Glove , Patient Examination , Latex
15. **Description of the Device:**

Non-Sterile, powder-free latex examination gloves and protein claim (50 micrograms or less).

16. **Intended use of the device:**

This device is a disposable device intended for medical purpose that is worn on the examiner 's hand to prevent contamination between patient and examiner.

17. **Summary of The Technological Characteristics of The devices :(According Guidance for Industry and FDA Staff - Medical Glove Guidance Manual(January 22, 2008))**

Non-Sterile, powder-free latex examination gloves and protein claim (50 micrograms or less) are summarized with the following technological characteristics:

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions: overall length; width, palm and finger thickness	ASTM D 3578-05-e1	Meets
Tensile strength: before and after aging	ASTM D 3578-05-e1	Meets
Ultimate elongation: before and after aging	ASTM D 3578-05-e1	Meets
Freedom from holes: pinholes AQL 2.5	ASTM D 3578-05-e1	Meets
Powder Free Residue	ASTM D 3578-05-e1	Meets
Protein Level	ASTM D 3578-05-e1	Meets
Biocompatability	Primary Skin Irritation in Rabbits	Passes
	Guinea Pig Sensitization	Passes

K 100401

18. Substantial Equivalents Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

19. Conclusion

It can be concluded that Non-Sterile, powder-free latex examination gloves and protein claim (50 micrograms or less) will perform according to the glove performance standards referenced in section 17 above and meet ASTM standards, and FDA requirements. Consequently, this device is substantially equivalent to currently marketed devices.This device is safe and effective as the predicate device *Siam Sempermed Latex Patient Examination Glove , Powder free and protein claim (50 micrograms or less).* Indeed , it is equivalent.This is better expressed in the tabulated comparison as below.

Technical comparison of specific elements is attached in the main submission.

FDA file reference number	510k number : K970794
Attachments inside notification submission file	REFER TO APPENDIX 1
TECHNOLOGICAL CHARACTERISTICS	*Comparison result* **REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Similar
Performance	Identical
Sterility	Not applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (Not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (Not applicable)
Thermal safety	Identical (Not applicable)
Radiation safety	Identical (Not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 9 2010

Siam Sempermed Corporation, Limited
C/O Mr. William E. Harris
President & Chief Executive Office
Sempermed USA, Incorporated
13900 49th Street North
Clearwater, Florida 33762

Re: K100907
Trade/Device Name: Non-Sterile, Powder-Free Latex Examination Glove with Protein Claim (50 micrograms or less)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: June 16, 2010
Received: June 22, 2010

Dear Mr. Harris:

This letter corrects our substantially equivalent letter of July 9, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100907

Device Name: Non-Sterile, Powder-Free Latex Examination Glove with Protein Claim (50 micrograms or less).

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100907

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)